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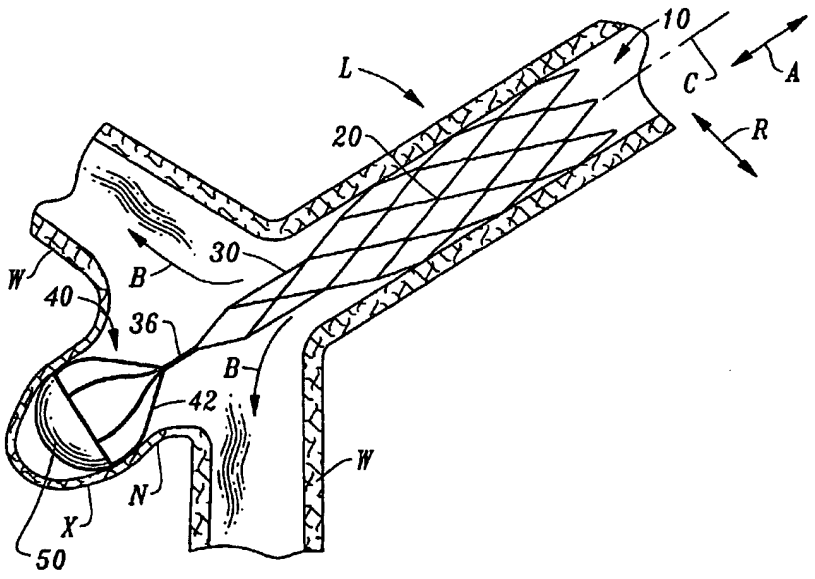
(54) Title: RADIALLY EXPANDABLE ANEURYSM TREATMENT STENT



(57) Abstract: A radially expandable stent is provided for treatment of aneurysms. The stent can take on a variety of configurations such as a blunt tip stent (10) or a faceted tip stent (110). A tip (40) or faceted tip (120) are provided which extend at least partially into the aneurysm (X, X') and are radially expanded therein to oppose blood flow B into the aneurysm (X, X'). The tip (40, 120) can be utilized alone or supported by a cylindrical base (20) which is radially expanded within a body lumen (L) adjacent the aneurysm (X, X') to securely hold the tip (40, 120) in position. The tip (40) includes ribs (42) which provide structural support for a cap (50) which diverts blood flow B from passing into the aneurysm (X). The faceted tip (120) includes segments (122) with a flexible layer (130) there between and with the facets formed by the segments (122) spanned by the layer (130) extending in toward a centerline (C) of the faceted tip (120).

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RADIALLY EXPANDABLE ANEURYSM TREATMENT STENT

Technical Field

The following invention relates to surgically implantable structures for treatment of aneurysms. More particularly, this invention relates to surgically implantable structures which include surfaces that block a neck of the aneurysm to preclude fluid flow into the aneurysm and prevent further expansion and/or rupture of the aneurysm.

Background Art

Aneurysms are bulges in a body lumen, such as a blood vessel. Aneurysms are relatively common especially in the larger arteries throughout the body. Aneurysms are related to the absence of a muscular layer that makes up part of the blood vessels, that over time stretches and thins to create the aneurysm. Aneurysms can break resulting in internal bleeding and related complications.

Brain aneurysms are of particular concern because rupture of a brain aneurysm can cause a stroke or death. Studies have shown that between 1% and 5% of the general population have brain aneurysms and that four hundred thousand people in the United States have brain aneurysms of a significant size. While smaller aneurysms (under 6 millimeters) are very unlikely to bleed, approximately thirty thousand people in the United States suffer from an aneurysm rupture every year. It has been estimated that 60% of such ruptures result in death and 20% of such ruptures result in disability. Accordingly, a need exists for effective treatment to reduce the incidence of brain aneurysm rupture.

Known prior art techniques for treatment of aneurysms include direct surgery and endovascular surgery. With direct surgery, the aneurysm is accessed by making incisions in the skin and opening the skull to locate the aneurysm. The neck of the aneurysm is identified where the ballooned aneurysm connects to the blood vessel. Typically the aneurysm is repaired by placing a clip across the neck. Blood flow is then restricted from passing into the aneurysm and continuing to cause ballooning of the aneurysm, which leads to rupture.

With endovascular surgery a catheter enters the body, typically through a leg artery, and is passed up to the location of the aneurysm under x-ray guidance. The aneurysm is then filled to decrease or eliminate blood flow into the aneurysm, which leads to aneurysm rupture. It is known in the prior art to fill the aneurysm with tiny coils of material or to fill tiny latex or silicone balloons

within the aneurysm.

United States Patent No. 5,350,397 is directed to an axially detachable embolic coil assembly which can be discharged from a catheter and used to fill an aneurysm. Other known prior art coil assemblies are disclosed in the following United States patents: 5,217,484; 5,234,437; 5,250,071; 5,261,916; 5,263,964; 5,562,698; 5,578,074; and 5,601,600.

While direct surgery and use of aneurysm clips is generally effective, it requires invasive surgery and the attendant discomfort and risk of complications. While endovascular surgery is less invasive and can more effectively access some blood vessels and other body lumens, the known technique of filling the aneurysm with coils or balloons is not entirely satisfactory. Specifically, when the coils are utilized a risk of displacement exists and the coil can come out of the aneurysm and do damage within the blood vessel, including causing a stroke. The coils are not affixed in any manner within the aneurysm, enhancing this risk. When coils and balloons are utilized to fill the aneurysm, some risk exists that the aneurysm will rupture during the endovascular procedure. For instance, when the coil is released the coil can put sufficient stress on the aneurysm wall to cause the aneurysm to rupture. Similarly, while the balloon is being filled within the aneurysm, it can be overfilled and cause the aneurysm to rupture. Accordingly, a need exists for a new method and apparatus for treatment of aneurysms.

Disclosure of Invention

The stent of this invention includes a plurality of segments and/or ribs which are coupled together at junctions in a manner which allows the segments/ribs to flex relative to each other and cause the stent to radially expand. The stent is first positioned intraluminally at the site where implantation is desired, while the stent is held in a collapsed form within a delivery tube which resists radial expansion of the stent. When the stent is released from the delivery tube a tip of the stent is located adjacent to the aneurysm, and typically at least partially through a neck of the aneurysm and into the aneurysm itself. When the stent is radially expanded this tip is held in position adjacent the neck of the aneurysm.

At least a portion of the tip of the stent includes some form of surface which extends between the segments and/or ribs within the tip of the stent. This surface opposes blood flow into the aneurysm. This opposition has the immediate effect of protecting the aneurysm from further expansion and rupture. Additionally, with the reduced blood flow, the conditions are desirable for restenosis adjacent the tip of the stent for further blockage of blood flow into the aneurysm. Because the stent has a radially expandable characteristic and is biased toward its radially expanded configuration, the stent is securely held in place and risk of displacement of the stent is avoided.

The tip of the stent can be used alone and be radially expanded against the neck of the aneurysm to hold itself in place. Alternatively, the tip can be coupled to a cylindrical base which is located

within a generally cylindrical luminal section adjacent the aneurysm, where the cylindrical base can be radially expanded to securely hold its position relative to the adjacent body lumen. With this alternative configuration the tip need not itself expand securely up against the neck of the aneurysm, but rather can freely rest within the aneurysm with secure support of the tip provided by the cylindrical base of the stent. If the aneurysm has an appropriately bulbous contour with the neck sufficiently smaller in diameter than other portions of the aneurysm, the tip can be provided alone and radially expanded within the aneurysm to a diameter greater than that of the neck, such that the tip is prevented from escape out of the aneurysm and does not place any forces upon the aneurysm which might lead to rupture.

The surface on the tip can be formed in a variety of ways, such as by providing a concave foam cap with ribs provided to give structural support to the cap. Alternatively, the cap can be formed from a flexible polymeric hydrocarbon, such as parylene. An interior of the cap can optionally be filled with a gel which expands and hardens somewhat when coming into contact with water containing fluids, such as blood. The ribs are provided with a bias toward a curved contour which supports the cap in a spherical or other expanded configuration.

The surface can alternatively be provided by multiple facets separate with a layer of material such as parylene spanning the facets. When such a faceted tip stent is radially expanded a plurality of distal corners of the facets remain together so that a closed tip with the surface layer spanning the facets between segments provides the surface for opposition of blood flow into the aneurysm. The material forming the segments is biased toward this final configuration for the faceted tip. Most of the segments are configured to follow a cylindrical contour. However, segments adjacent the distal corners are biased toward a configuration which converges in toward a central axis of the stent, such that when the faceted tip is released from the delivery tube it automatically deploys in the desired fashion to oppose blood flow into the aneurysm.

Brief Description of Drawings

Figure 1 is a side elevation view of a tip of an aneurysm treatment stent of this invention with the tip being utilizable either alone or in conjunction with a cylindrical base (Figures 6 and 7), and with the tip including a cap thereon for opposing blood flow into an aneurysm.

Figure 2 is a sectional view of the cap portion of Figure 1.

Figure 3 is a side elevation view of a portion of the stent of this invention when collapsed into a delivery tube.

Figure 4 is a full sectional view of a portion of the delivery tube shown in Figure 3 with the tube exhibiting a slightly less tapering contour and shown without the stent.

Figure 5 is a full sectional view of a portion of an alternative delivery tube to that which is shown in Figures 3 and 4.

Figure 6 is a side elevation view of a portion of the stent of this invention including the tip attached to the cylindrical base.

Figure 7 is a top plan view of the stent which is shown in Figure 6 with the stent deployed within a body lumen with the tip expanded within an aneurysm in the body lumen.

Figure 8 is a top plan view of a body lumen with a tip only expanded within an aneurysm having a width greater than a width of a neck of the aneurysm, and where the stent does not include the cylindrical base.

Figure 9 is a side elevation view of a first alternative embodiment of that which is shown in Figure 1.

Figure 10 is a side elevation view of a second alternative embodiment of that which shown in Figure 1.

Figure 11 is a cylindrical projection of a faceted tip which can either be utilized alone or in conjunction with a faceted tip stent including a cylindrical base.

Figure 12 is a cylindrical projection of that which is shown in Figure 11 before radial expansion as shown in Figure 11.

Figure 13 is a side elevation view of that which is shown in Figures 11 and 12, after radial expansion of the stent.

Figure 14 is a front elevation view of that which is shown in Figure 13.

Figure 15 is a top plan view of a body lumen with the stent of Figure 13 implanted within an aneurysm located in the body lumen.

Figure 16 is a top plan view of a body lumen with a faceted tip stent including both a faceted tip and a cylindrical base implanted within the body lumen with the faceted tip adjacent a neck of the aneurysm and blocking blood flow into the aneurysm.

Figure 17 is a perspective view of that which is shown in Figure 16.

Figure 18 is a cylindrical projection of that which is shown in Figure 17.

Figure 19 is a side elevation view of that which is shown in Figure 17.

Figure 20 is a cylindrical projection of a variation on the stent tip shown in Figure 11 where the bend line passes through junctions.

Figure 21 is an end elevation view of that which is shown in Figure 20.

Figure 22 is a perspective view of an alternative stent to that which is shown in Figure 17 with the bend line provided as shown in Figure 20.

Best Modes for Carrying Out the Invention

Referring to the drawings, wherein like reference numerals represent like parts throughout the various drawing figures, reference numeral 10 is directed to blunt tip stent (Figures 6 and 7) for implantation within a body lumen L adjacent an aneurysm X so that a tip 40 (Figures 1-7) can

oppose blood flow B into the aneurysm X. When blood flow B into the aneurysm X is opposed, the aneurysm X is prevented from further expanding and rupture and effective treatment of the aneurysm X is provided.

In essence, and with particular reference to Figures 1-7, basic details of the blunt tip stent 10 are described. The blunt tip stent 10 includes a cylindrical base 20 which has a generally cylindrical contour about a central axis C and is sufficiently radially expandable to engage walls W of a body lumen L for secure placement within the body lumen L. An extension 30 extends from a distal end 28 (Figure 6) of the cylindrical base 20. A tip 40 is attached to the extension 30. the tip 40 has a plurality of ribs which are biased toward a curved configuration as they extend from an attached end 44, where the ribs 42 are all joined together, to a free end 46 where the ribs 42 are spaced from each other. A cap 50 has a perimeter 56 thereof held open by the free ends 46 of the ribs 42 which are embedded into bores 58 within the cap 50. The cap 50 can be formed from an open-celled foam material, or can be formed from other bio-compatible flexible materials, such as parylene. An interior 60 can be optionally filled with a gel having an ability to expand and solidify somewhat when coming into contact with water containing materials such as blood.

The blunt tip stent 10 can be radially collapsed, along arrow R (Figure 6) sufficiently so that the stent 10 can be oriented within a delivery tube 100 (Figures 3-5). The delivery tube 100 is flexible to allow routing through small and sharply curving luminal pathways, such as blood vessels within the brain, and resists radial expansion due to forces generated by the stent 10 as it seeks its biased radially expanded configuration. When the delivery tube 100 is retracted relative to the stent 10, the stent 10 transitions from its first radially collapsed configuration to its second radially expanded configuration where it engages walls W of the lumen L and opposes blood flow into the aneurysm X.

More specifically, and with particular reference to Figures 1 and 2, details of the tip 40 for the blunt tip stent 10 are described. The tip 40 can either be provided as one portion of the blunt tip stent 10 or can function alone as a radially expandable aneurysm treatment stent (Figure 8). While various different medical criteria might indicate the use of the tip 40 alone rather than in conjunction with the cylindrical base 20 and other portions of the blunt tip stent 10, a primary factor is the configuration of the aneurysm X. If the aneurysm X is characterized by having a neck 10' (Figure 8) which is narrower than a diameter of the aneurysm X' (Figure 8) the tip 40 can be provided with a diameter which is less than a diameter of the aneurysm X' and greater than the diameter of the neck N'. The tip 40 can be expanded within the aneurysm X' and be trapped within the aneurysm X' due to the smaller size of the neck N'. However, the tip 40 diameter being less than the diameter of the aneurysm X' ensures that forces are not exerted on the aneurysm X' by the tip 40 which might cause rupture or other damage to the aneurysm X'.

Where the aneurysm X has a more tapering configuration with a neck N which is similar in diameter or larger than a diameter of the aneurysm X, the tip 40 is less able to hold its own position within the aneurysm X. Use of the tip 40 in conjunction with the cylindrical base 20 of

the blunt tip stent 10 is thus indicated, with the cylindrical base 20 radially expanded against walls W of the body lumen L adjacent the aneurysm X so that the cylindrical base 20 of the blunt tip stent 10 securely holds the tip 40 within the aneurysm X. It is not necessary that the tip 40 extend all the way into the aneurysm X. Rather, it is merely necessary that the tip 40 be located sufficiently within or beyond the neck N that blood flow B is diverted from passing into the aneurysm X and kept within the desired luminal pathways.

While the tip 40 can take on a variety of different configurations structurally, the tip 40 first requires a configuration which facilitates radial expansion between a first collapsed diameter and a second radially expanded diameter, along arrow R (Figure 1). Second, the tip 40 must have some form of surface which is oriented to be non-parallel to the central axis C of the tip 40 so that the surface at least partially opposes blood flow B into the aneurysm X when the tip 40 is located adjacent the aneurysm X.

Preferably, the tip 40 includes a plurality of ribs 42 which each include an attached end 44 and a free end 46. Each of the ribs 42 are joined together at their attached ends 44 and are spaced from each other at their free ends 46. Each of the ribs 42 follows a curving contour with the ribs 42 generally adjacent the central axis C at the attached end 44 and extending out radially as the ribs 42 extend axially toward the cap 50.

The ribs 42 can be formed from a shape memory material, such as nickel titanium, with the ribs 42 biased toward their final curving contour. Details of use of nickel titanium shape memory materials are described in United States Patent No. 6,042,606, incorporated herein by reference. When the ribs 42 are cooled below a transition temperature, as is known in the art, the ribs 42 can be easily oriented axially, along arrow A, and collapsed along with other portions of the tip 40 before implantation. When the ribs 42 are heated above their transition temperature and released from the delivery tube 100 or other restraint, the ribs 42 assume their biased curving configuration (Figure 1) and deploy the cap 50.

The cap 50 is preferably a concave structure having a substantially constant wall thickness between the inside surface 52 and an outside surface 54 (Figure 2). A perimeter 56 defines an edge of the cap 50 into which the free ends 46 of the ribs 42 extend. Bores 58 receive the free ends 46 of the ribs 42 therein. An interior 60 is thus provided by the cap 50. The cap 50 is preferably formed from an open-celled foam material which is sufficiently flexible and compressible to be compressed down into the delivery tube 100, and sufficiently flexible and resilient to return to its substantially hemispherical concave form after release from the delivery tube 100. The ribs 42 additionally encourage the foam forming the cap 50 to return to the desired, substantially spherical concave form, when the tip 40 is released from the delivery tube 100.

When the cap 50 is formed from an open-celled foam, this foam can be impregnated with a gel material which is capable of expansion and hardening when exposed to water within body fluids. One such gel is Tecogel 2000, provided by Thermedics, Inc. of Woburn, Massachusetts. The gel can be both within the cells of the foam cap 50 or within the interior 60 of the concave cap 50, or

both. The hardened gel further discourages blood flow B into the aneurysm X. Various different foams are available having varying densities and varying different open cell sizes and with varying different hardnesses to suit the desires of the medical professional. The foam desirably avoids providing damagingly high pressure against the aneurysm X, while providing a structure which diverts blood flow B away from the aneurysm X and provides a structure which can encourage restenosis.

As an alternative, the cap 50 can be formed from a flexible layer of non-permeable material. For instance, the cap 50 can be formed from parylene. This parylene film can be between 0.0001 and 0.002 inches thick, with 0.0005 inches considered an ideal thickness.

Parylene is the generic name for members of a family of polymeric di-para-zylylenes. Parylene refers to such thermoplastic polymers that can be formed on surfaces exposed to a rarefied gas in a vacuum. To create the surface layer forming the cap 50, the parylene can be deposited onto a mandrel or other deposition surface laying adjacent where the cap 50 is to be formed during the vacuum deposition process. Alternatively, a thin flexible base layer can be located where the cap 50 is to be formed and then the parylene can be deposited directly onto this base layer to create the parylene surface layer forming the cap 50. If desired, the entire stent 10, including the segments 22, junctions 24 and ribs 42 can be coated with the parylene that forms the surface layer also.

As an alternative, the surface layer forming the cap 50 can be formed as a silicone film or from high strength copolymers of silicone and a polycarbonate, such as products marketed under the trademark Chronoflex manufactured by Cardiotech International, Inc. of Woburn, Massachusetts. Other appropriate materials, such as polyesters or polytetrafluoroethylene, or any other appropriate flexible surface materials can be utilized to create the surface layer forming the cap 50.

Two alternative configurations for the tip 40 are provided in Figures 9 and 10. Figure 9 depicts a first alternative tip 240 which is similar to the tip 40 of the preferred embodiment except that the ribs 42 are replaced with longer ribs 242 which extend all the way back to the center line C where the free ends 246 of the ribs 242 are then joined together. The ribs 242 thus are coupled together both at their attached ends 244 and at their free ends 246 which join together within the cap 50. This first alternative tip 240 includes additional structural support provided by the longer ribs 242.

The second alternative tip 340 includes ribs 342 which have attached ends 344 joined together and free ends 346 which are also joined together within the cap 50. With the second alternative tip 340, the ribs 342 do not terminate facing in toward each other, but rather bend back toward an orientation parallel to the central axis C before terminating at the free ends 346. Numerous different variations and different patterns for ribs 42, 242, 342 can be provided to provide additional structural support for the tips 40, 240, 340 and for the cap 50, and to provide desirable flexibility, radiopacity, geometry and other characteristics desired by the medical professional.

If the tip 40 is utilized in conjunction with other portions of the blunt tip stent 10 (Figures 6 and 7), the attached end 44 of the ribs 42 would be joined to a bridge 36 of the extension 30. The extension 30 includes segments 22 and junctions 24 following a pattern similar to that for the

cylindrical base 20 with the exception that axial segments 32 are preferably provided to enhance rigidity of the extension 30. The extension 30 spans a gap 34 with minimal blockage of the gap 34. Hence, blood flow B (Figure 7) is not blocked between different pathways of the body lumen L. The bridge 36 couples to the segments 22 forming the extension 30 so that the tip 40 is secured to the cylindrical base 20.

With particular reference to Figures 6 and 7, specific details of the cylindrical base 20 of the stent 10 are described. The base 20 exhibits a generally cylindrical form with a plurality of segments 22 extending between junctions 24 to make up the cylindrical form of the base 20. The cylinder formed by the base 20 is not walled or enclosed. Rather, the segments 22 and junctions 24 are merely located so that they each lie in a manner which, when they are all considered together, lie along a common substantially cylindrical contour.

Stents have been proposed and manufactured having a variety of different segment and junction configurations. For instance, a single segment can extend helically to form a cylindrical stent. A full discussion of various stent segment patterns is provided in *Handbook of Coronary Stents*, Second Edition. Any of the prior art stents disclosed in that reference or otherwise known in the prior art which exhibit radial expandability could conceivably be adapted for use within the stent 10 of this invention.

For convenience, a base 20 having a multiple linear segment 22 pattern is provided with junctions 24 between ends of each of the segments 22. The segments 22 are oriented substantially axially (along arrow A of Figure 6) before radial expansion, along arrow R of Figure 6 (see portions of the base 20 located within the delivery tube 100 of Figure 3). When the base 20 is radially expanded, along arrow R, the segments 22 transition into an orientation which is less axially aligned.

Preferably, the base 20 radially expands to the point where the segments 22 diverge from an axial orientation by 19° when the base 20 is radially expanded. Preferably, each segment 22 extends approximately 0.1000 inches axially when the base 20 is radially expanded. Each segment 22 preferably is 0.0020 inches thick with areas of increased stress optionally made thicker (i.e. 0.0030 inches thick). The base 20 preferably has a compressed diameter of 0.012 inches and an expanded diameter of 0.120 inches. When radially expanded, the length and width of the segments 22, along with the expanded angular deviation from axial orientation of 19° provides the base 20 with an approximately ten times expansion coefficient. Of course the amount of radial expansion, along arrow R of Figure 6, can be increased by increasing the length of the segments 22 or by increasing an amount of angular displacement of the segments 22 away from the axial orientation when radially expanded.

The segments 22 and junctions 24 which form the stent 10 can be made from a variety of different bio-compatible materials. Preferably however, the segments 22, junctions 24 and ribs 42 of the stent 10 are formed from a shape memory nickel titanium alloy. Such nickel titanium alloys are unique in that they can be treated in a manner which gives the stent a preferred form to which

the stent 10 is biased, when a particular temperature, in this case body temperature, is attached. When the stent 10 is cooled to below a transition temperature, the stent 10 becomes much more malleable and can be easily collapsed. When the stent 10 is heated back to its transition temperature, it elastically seeks the form for which it was originally biased. The details associated with the formation and biasing of such shape memory stents are disclosed in detail in United States Patent No. 6,042,606, incorporated herein by reference. Alternatively, the stent 10 can be formed from plastically deformable metal alloys, such as stainless steel.

With particular reference to Figures 11-19, details of a faceted tip stent 110 are described. As with the blunt tip stent 10 described previously, the faceted tip stent 110 can either be utilized with the faceted tip 120 alone or with the faceted tip 120 in conjunction with a cylindrical base 20 and extension 30 identical to the cylindrical base 20 and extension 30 described in detail above.

The faceted tip 120 is preferably formed from a plurality of segments 122 joined together at junctions 124. Angles at which the segments 122 join to the junctions 124 are flexibly adjustable to allow the faceted tip 120 to radial expand and contract relative to the central axis C (Figures 11-13). The segments 122 extend at one end of the tip 120 to distal corners 126 and at another end of the faceted tip 120 to proximal corners 128. The faceted tip 120 preferably maintains a substantially cylindrical contour defined by the orientation of the segments 122 and junctions 124 except adjacent the distal corners 126.

A bend line 129 is provided which defines a location where the segments 122 extend away from the cylindrical contour and in toward the central axis C. Preferably, the segments 122 extend in toward the central axis C sufficiently so that the distal corners 126 are adjacent each other and adjacent the central axis C (Figure 13). As discussed in detail above, the segments 122 can be formed from appropriate shape-memory materials, such as nickel titanium, so that the segments 122 are biased toward this configuration, as shown in Figure 13.

When the faceted tip 120 is radially expanded, the distal corners 126 would remain adjacent the central axis C and other portions of the faceted tip 120 would radially expand (along arrow R) to form the desired configuration. If necessary to maintain the distal corners 126 adjacent the centerline C, the distal corners 126 can be welded together or held together with a fastener coupling the distal corners 126 together.

Space between segments 122 which join together at the distal corners 126 is preferably spanned by a layer 130, such as the parylene layer discussed in detail above. This layer 130 extends all the way into the distal corner 126 and out to a proximal edge 132. The proximal edge 132 is preferably adjacent to the bend line 129 at which the segments 122 diverge from the cylindrical contour and in toward the centerline C. As shown in Figure 14, the layers 130 between the segments 122 which extend to the distal corners 126 will cause approximately half of the faceted tip 120 to be closed by the layer 130. Blood flow B is thus disrupted so that it cannot freely pass into the aneurysm X without opposition and will decrease pressure on the aneurysm X which would otherwise tend to expand and encourage rupture of the aneurysm X.

When the faceted tip 120 is utilized in conjunction with the faceted tip stent 110, at least some of the proximal corners 128 are joined to portions of the extension 30 (Figures 17-19) so that the faceted tip 120 can be securely held in position relative to aneurysms X which are not appropriately configured to allow a faceted tip 120 to securely hold within the aneurysm X without additional support provided by the cylindrical base 20. As with the blunt tip stent 10 discussed previously, the faceted tip stent 110 includes the gap 34 adjacent the extension 30 so that blood flow B between side branches adjacent the aneurysm X is not disrupted by the cylindrical base 20 of the faceted tip stent 110, which is within the lumen L to hold the faceted tip 120 in position.

With particular reference to Figures 20-22, a first alternative to the faceted tip stent 110 is provided. This alternative faceted tip stent 410 is similar to the faceted tip stent 110 of the preferred embodiment except that it has a unique first alternative faceted tip 420. Specifically, this alternative faceted tip 420 has a bend line 429 which passes through junctions 424 rather than with the faceted tip 120 where the bend line 129 passes through segments 122. With this first alternative faceted tip 420 a surface layer 430 extends from a distal corner 426 to the bend line 429. With the facets covered by the layer 430 extending all the way from junctions 426 to the distal corners 426, and with these facets extending in toward the center line C of the alternative stent 410, the entire distal end of the alternative faceted tip 120 is substantially closed by the facets covered with the layer 430. This alternative faceted tip 420 illustrates a second of many conceivable alternative configurations for the faceted tip stent 110, 410. Where the faceted tip 120, 420 is desired to have a more blunt distal corner 126, 426, the bend line 129, 429 can be moved closer to the distal corner 126, 426. Where avoidance or minimization of gaps between facets covered with the layer 130, 430 is desired, the bend line 129, 429 is moved toward the junctions 424 which are closest to the distal corners 426.

In use and operation, and with particular reference to Figures 7, 8, 15 and 16, details of the use and operation of this invention are described. Initially, a medical professional would utilize appropriate diagnostic techniques to identify aneurysms X, X' to be treated. When an aneurysm X, X' has been selected which requires treatment, the size and contour of the aneurysm X, X' will be evaluated. Based on this evaluation, the medical professional will choose a stent 10, 110 and stent tip 40, 120 having a size and configuration which will most effectively oppose blood flow into the aneurysm X, X'. For instance, if the aneurysm X' has a large width and a small neck N', the tip 40 (Figure 8) may be deployable alone to treat the aneurysm. If the medical professional is concerned about keeping the tip 40, 120 in the desired position, the medical professional may choose a stent such as the stent 10, 110 which includes the cylindrical base 20 for securely holding the tip 40, 120 in position.

Once the appropriate stent 10, 110 has been selected, it can be provided from a pre-manufactured set of stents 10, 110 or can be specially manufactured to the medical professional's specifications. When nickel titanium shape memory materials are utilized to form the segments 22, 122 and/or ribs 42 of the stent 10, 110, the structural elements are initially configured as desired

utilizing known techniques such as laser etching, and other techniques as specifically disclosed in United States Patent Application No. 6,042,606 incorporated herein by reference.

Once structural portions of the stent 10, 110 have been configured and heat treated to provide the desired transition temperature and biased orientation, the foam or other materials forming the cap 50 or layer 130 are coupled to the structural portions of the tip 40, 120. The stent 10, 110 is then cooled below its transition temperature and radially collapsed and inserted into the delivery tube 100. Utilizing intraluminal surgical techniques, the delivery tube 100 with the included stent 10, 110 or tip 40, 120 alone is routed to the stent delivery site. The delivery tube 100 is then retracted and the stent 10, 110 or tip 40, 120 alone is allowed to expand radially (along arrow R) in its desired final position. The stent 10, 110 or tip 40, 120 are then in position to oppose blood flow B into the aneurysm X, X' and the aneurysm X, X' is effectively treated.

This disclosure is provided to reveal a preferred embodiment of the invention and a best mode for practicing the invention. Having thus described the invention in this way, it should be apparent that various different modifications can be made to the preferred embodiment without departing from the scope and spirit of this disclosure. When structures are identified as a means to perform a function, the identification is intended to include all structures which can perform the function specified.

Industrial Applicability

This invention exhibits industrial applicability in that it provides a radially expandable stent which includes a covering surface which can be flexibly deployed when the stent is radially expanded to block a neck of an aneurysm, such as a brain aneurysm within a blood vessel.

Another object of the present invention is to provide a stent which can radially collapsed sufficiently to pass through small arterial pathways within a delivery tube, such as arterial pathways leading to brain aneurysm sites, and be radially expanded to a diameter sufficiently large to securely hold position within the blood vessel adjacent the aneurysm.

Another object of the present invention is to provide a stent for treatment of aneurysms which can be implanted without direct surgery and which can be securely held in position adjacent the aneurysm without imparting any damaging stresses upon the aneurysm itself which might cause rupture of the aneurysm.

Another object of the present invention is to provide a stent which can block an aneurysm in a blood vessel with a branching side pathway nearby and not block blood flow in the side pathway.

Another object of the present invention is to provide a stent which includes a covering tip which extends at least partially in towards the center line of the stent when the stent is radially expanded, such that a central pathway through the stent is at least partially blocked by the covering tip.

Another object of the present invention is to provide a radially expandable stent which can be implanted within a body lumen, such as a blood vessel, which is faced by a neck of an aneurysm and with various branches of the lumen on either side of the aneurysm with the stent covering the neck of the aneurysm and leaving the lumen branches substantially unobstructed adjacent the aneurysm.

Another object of the present invention is to provide a radially expandable stent which can have a tip thereof located within the aneurysm and which, when radially expanded at least partially opposes blood flow into the aneurysm.

Other further objects of the present invention will become apparent from a careful reading of the included drawing figures, the claims and detailed description of the invention.

CLAIMS

What is claimed is:

Claim 1 - A stent for treatment of an aneurysm in a body lumen, comprising in combination:

a tip having a first collapsed diameter less than a width of a neck of an aneurysm and a second expanded diameter greater than said collapsed diameter; and

said tip having a surface oriented at least partially non-parallel to a central axis of said tip, such that said surface at least partially opposes blood flow into the aneurysm.

Claim 2 - The stent of Claim 1 wherein said surface spans a majority of said second expanded diameter of said tip.

Claim 3 - The stent of Claim 2 wherein said surface is at least partially defined by a cap, and wherein ribs extend at least partially into said cap, said ribs formed from a material having a greater rigidity than a material forming said cap.

Claim 4 - The stent of Claim 3 wherein said cap is concave on an inside surface thereof with said ribs extending out of a perimeter of said cap with free ends of said ribs embedded within said cap and attached ends of said ribs joined together at a location spaced from said cap.

Claim 5 - The stent of Claim 4 wherein said cap is formed of an open cell foam material and wherein said cap is filled with a gel material which hardens and expands in volume when coming into contact with water.

Claim 6 - The stent of Claim 1 wherein said surface of said tip includes at least two layered facets with segments forming a perimeter of each facet and with a layer of flexible material extending between said segments to form said layered facets, said segments having a greater rigidity than said layer.

Claim 7 - The stent of Claim 6 wherein said segments of said tip are formed of shape-memory materials which are biased toward an expanded configuration corresponding with said second expanded diameter.

Claim 8 - The stent of Claim 7 wherein said segments together form a generally cylindrical contour except where said layered facets extend in toward said central axis of said tip when said tip is in said biased second position.

Claim 9 - The stent of Claim 8 wherein said segments forming said layered facets extend to distal corners where said segments of each layered facet are coupled together; and

wherein at least two layered facets are provided within said tip, said distal corners of at least two of said layered facets coupled together.

Claim 10 - The stent of Claim 9 wherein said distal corners of said layered facets are coupled together by welding.

Claim 11 - The stent of Claim 1 wherein said surface is sufficiently flexible to allow said tip to transition between said first collapsed diameter and said second expanded diameter.

Claim 12 - The stent of Claim 1 wherein said expanded diameter is less than a diameter of the aneurysm, such that said tip can expand within the aneurysm to said expanded diameter without putting expansion pressure upon the aneurysm.

Claim 13 - The stent of Claim 12 wherein said expanded diameter of said tip is greater than a diameter of the neck of the aneurysm, such that said tip can be held in place within the aneurysm after radial expansion of said tip to said second expanded diameter.

Claim 14 - A blunt tip stent for disrupting blood flow adjacent to an aneurysm, comprising in combination:

a plurality of ribs, said ribs joined together at first attached ends and diverging away from each other as they extend from said first attached ends; and

a cap coupled to portions of said ribs which diverge from each other and which are spaced from said attached ends, said cap oriented at least partially non-parallel to a central axis of said stent, such that said cap opposes blood flow into the aneurysm when the cap is located adjacent the aneurysm.

Claim 15 - The stent of Claim 14 wherein said cap is radially collapsible and wherein said ribs are radially collapsible.

Claim 16 - The stent of Claim 15 wherein said cap is made of a porous foam material.

Claim 17 - The stent of Claim 15 wherein said cap is made of a parylene material.

Claim 18 - A faceted tip stent for disrupting blood flow adjacent to an aneurysm, comprising in combination:

a plurality of segments joined together at junctions to form a generally cylindrical contour about a central axis of said stent;

at least two of said segments extending in toward said central axis; and

a surface layer coupled to said at least two segments extending in toward said central axis.

Claim 19 - The stent of Claim 18 wherein said at least two segments extending in toward said central axis are coupled together at a distal corner, wherein at least two distal corners are provided by different pairs of segments, said at least two distal corners located adjacent each other and adjacent said central axis.

Claim 20 - The stent of Claim 19 wherein said segments are formed from shape-memory materials which are biased toward an expanded configuration with said faceted tip having a generally cylindrical contour except where segments adjacent said distal corner extend in toward said central axis;

wherein a bend line is provided defining a location on said segments where said segments transition from a cylindrical contour to a contour extending in toward said central axis; and

wherein said layer is formed of sufficiently flexible material to allow said stent to transition between a radially expanded and radially collapsed diameter.

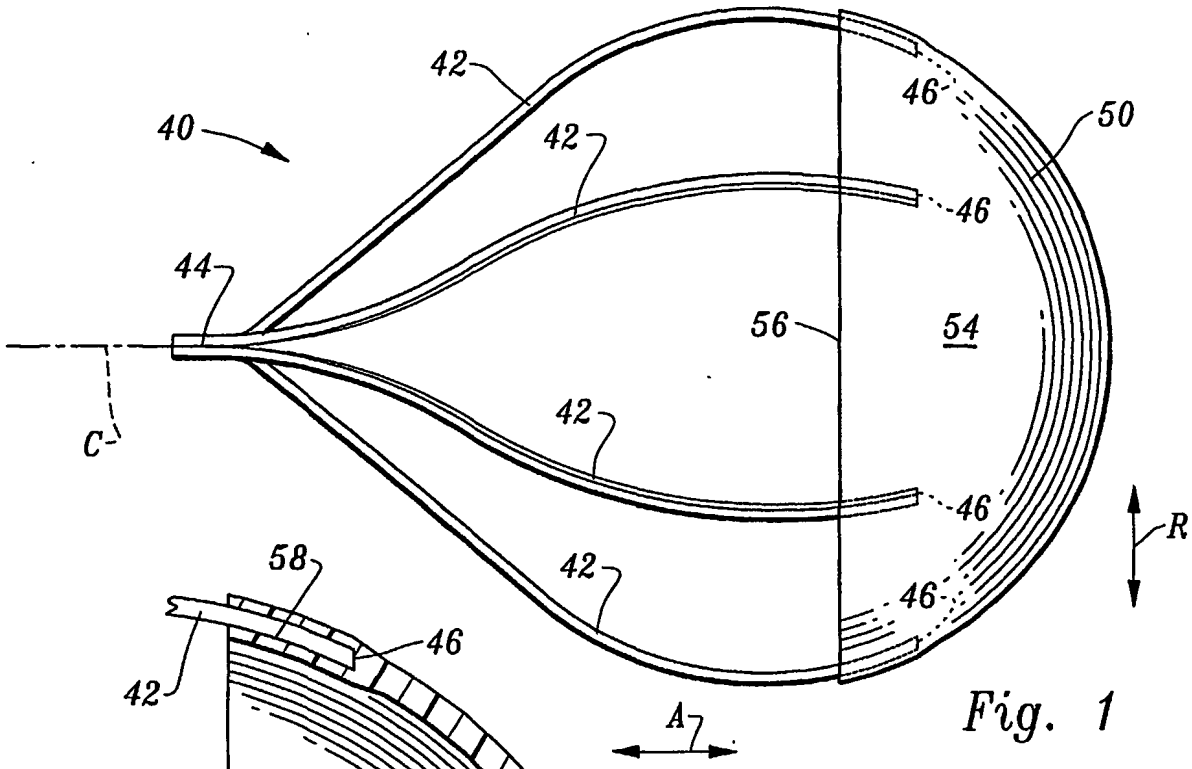
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Fig. 1

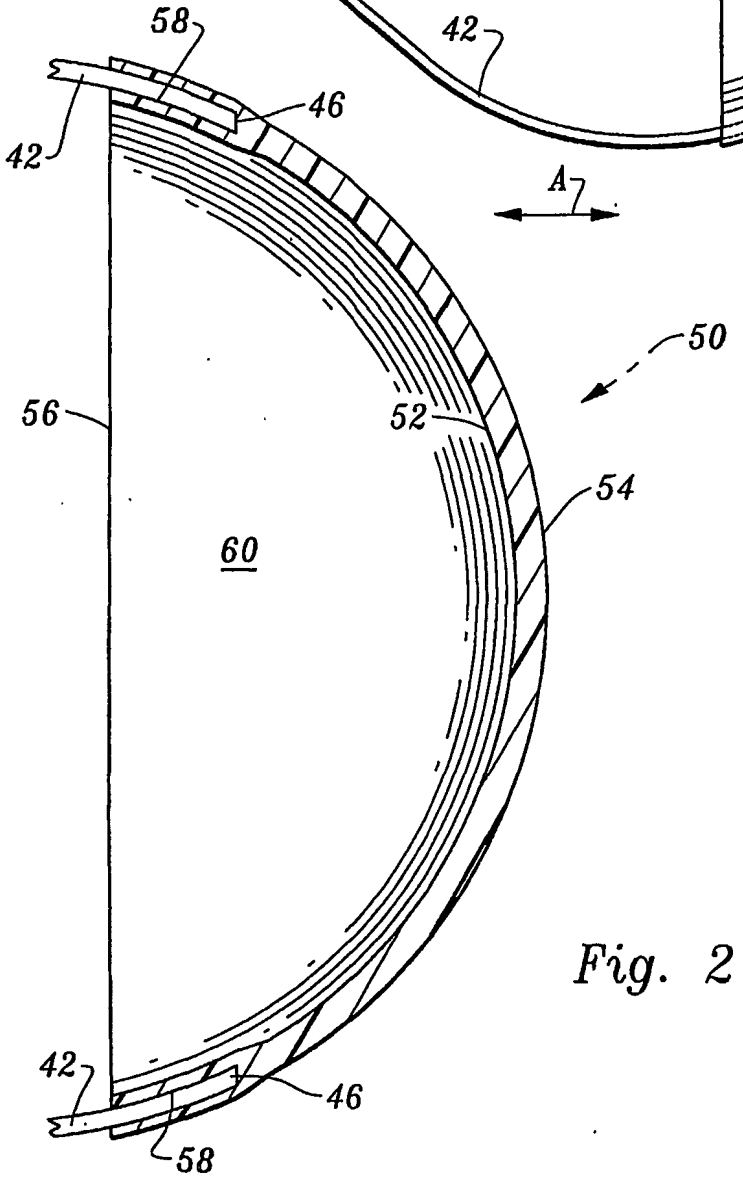
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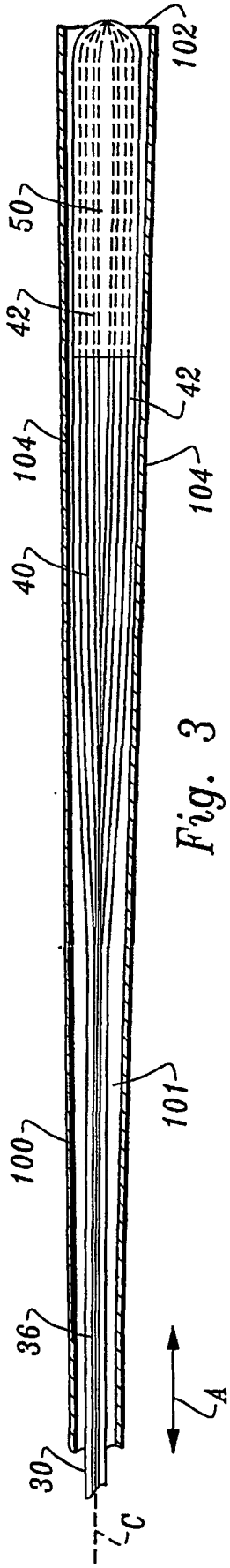
Fig. 2



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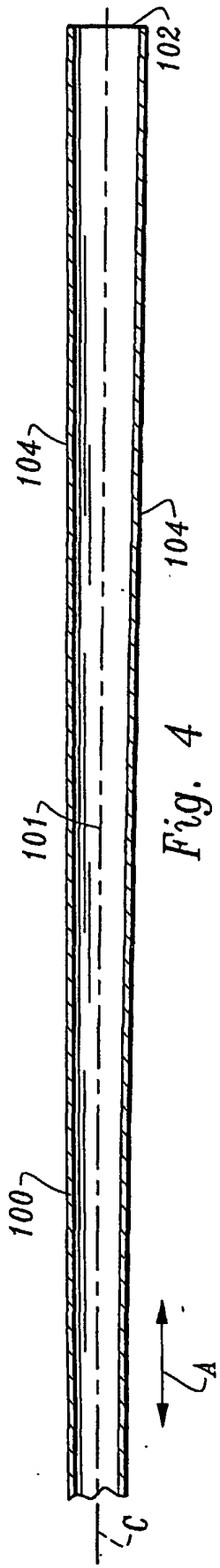

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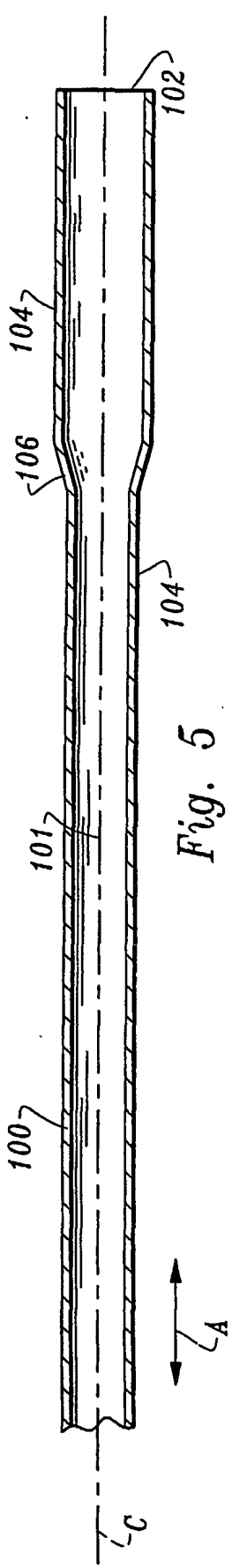

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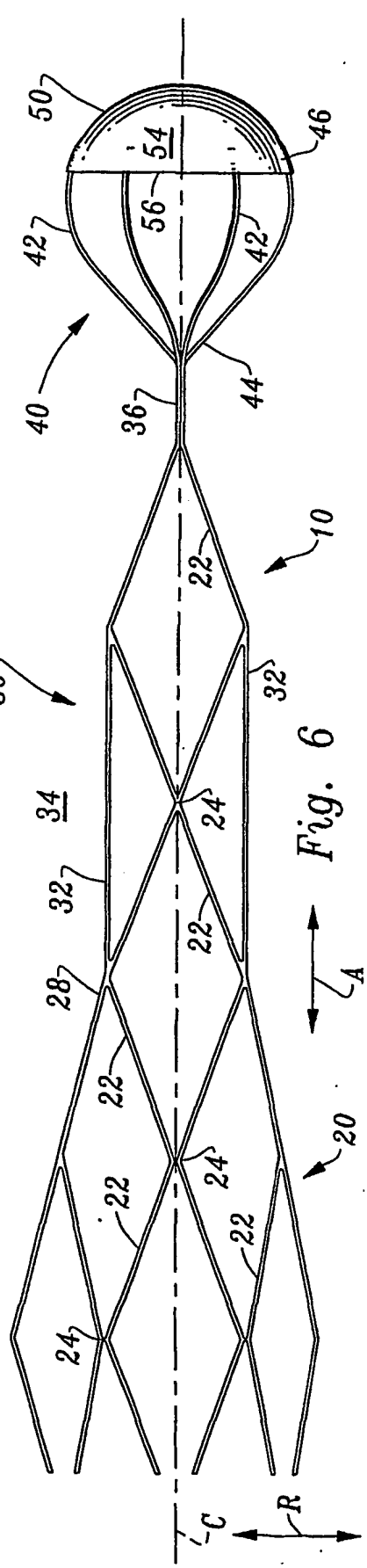

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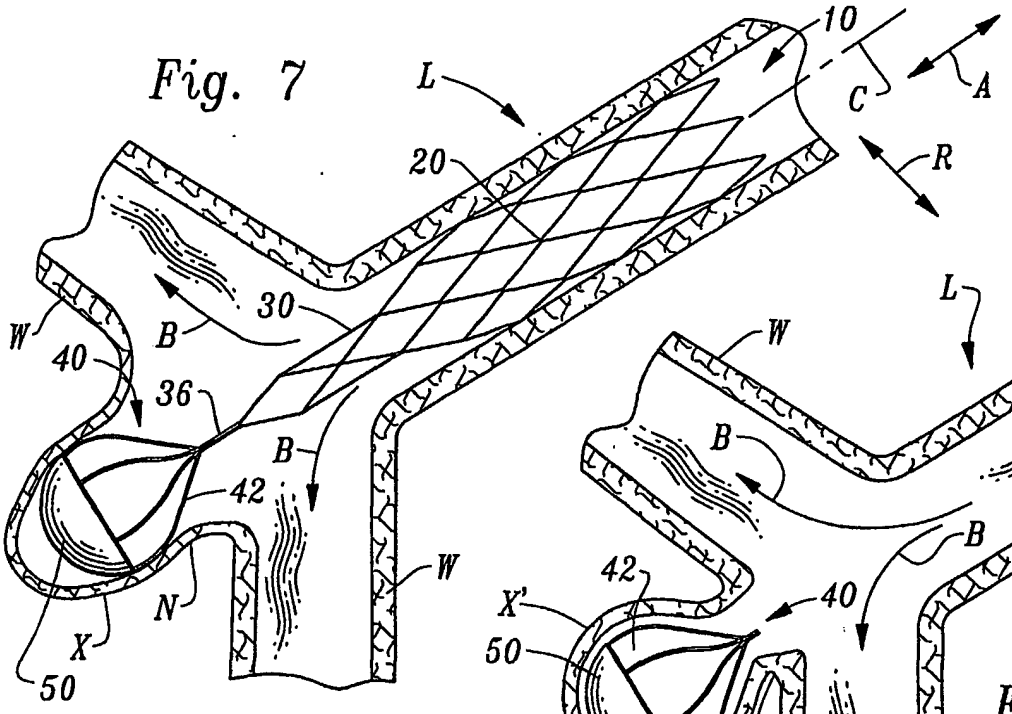
Fig. 7



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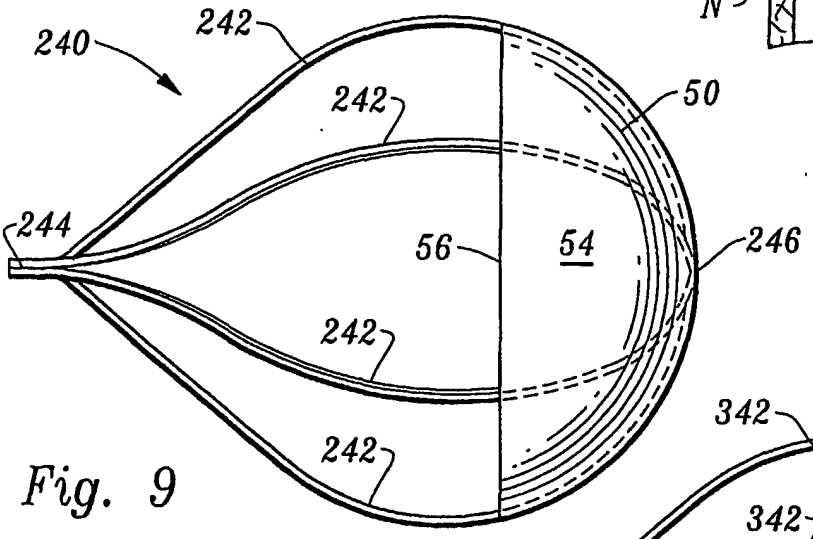

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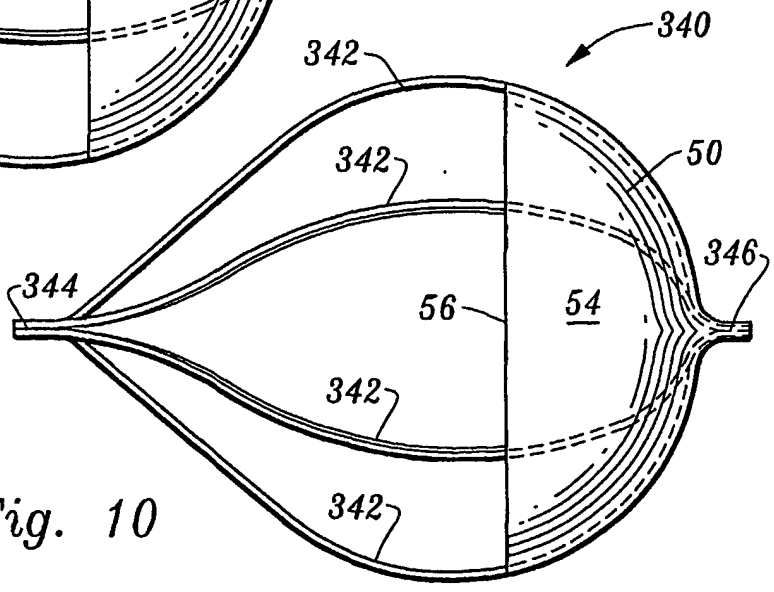

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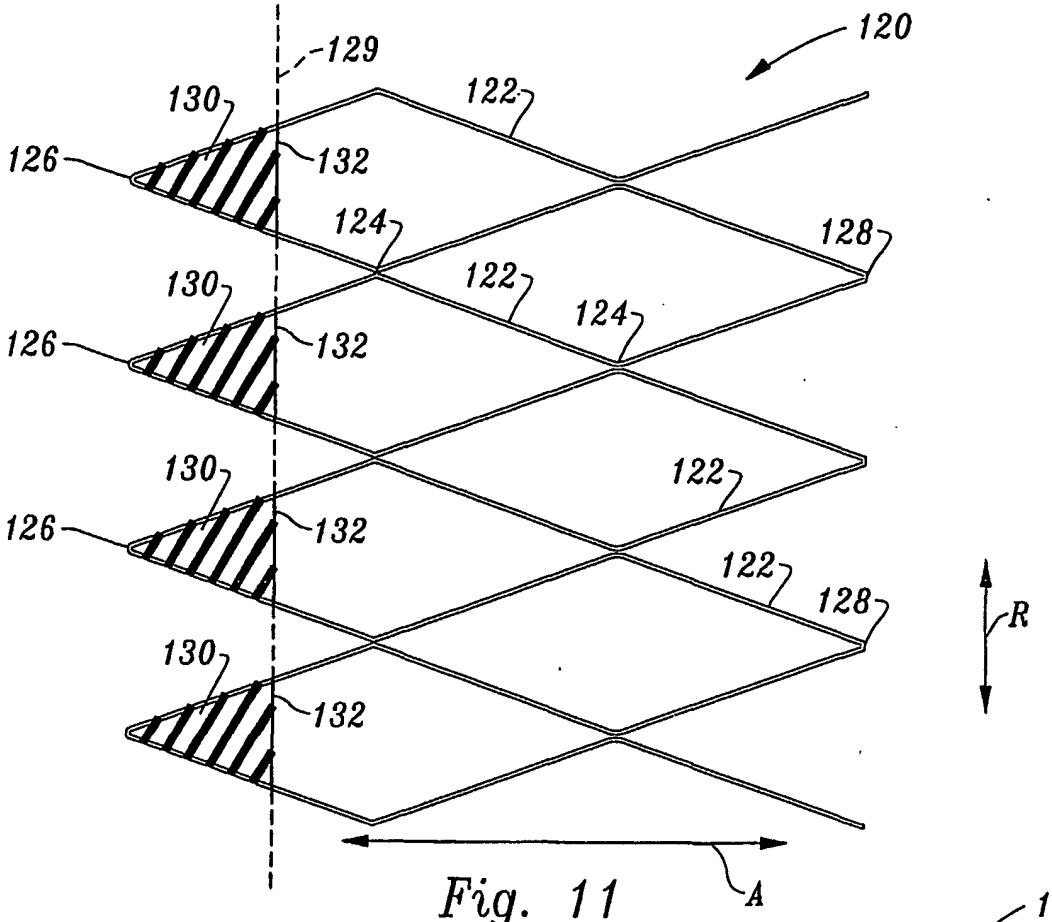

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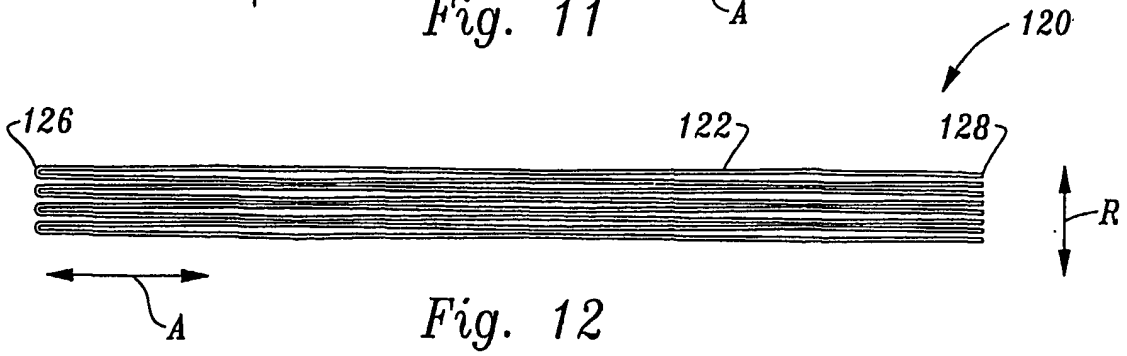

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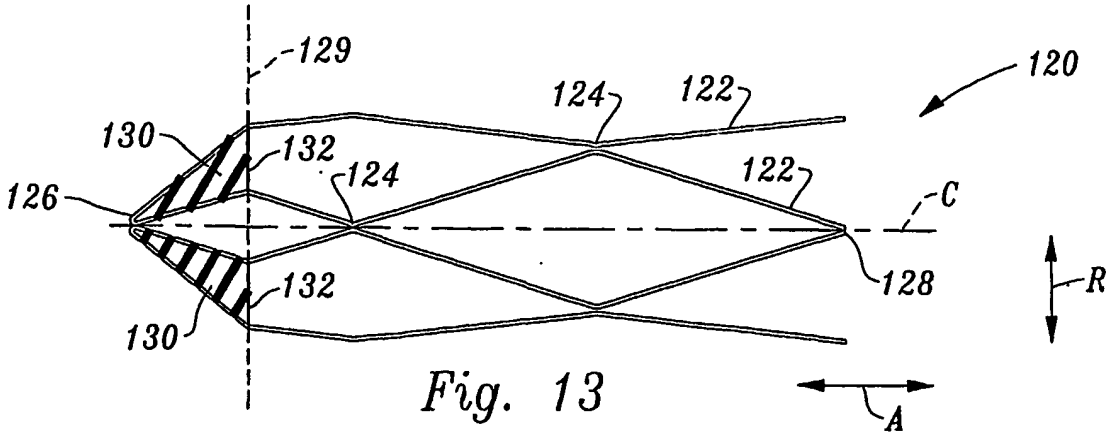

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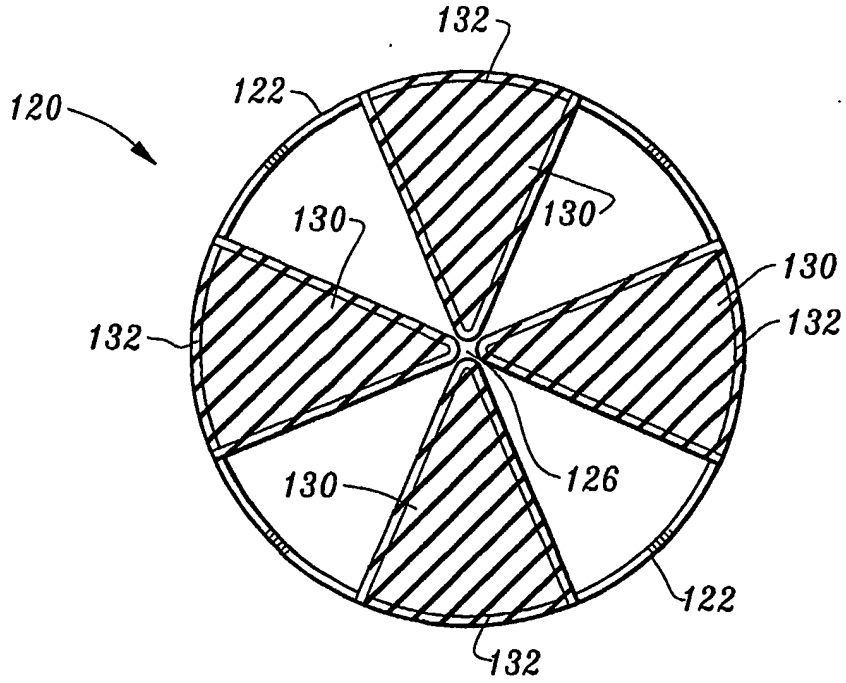

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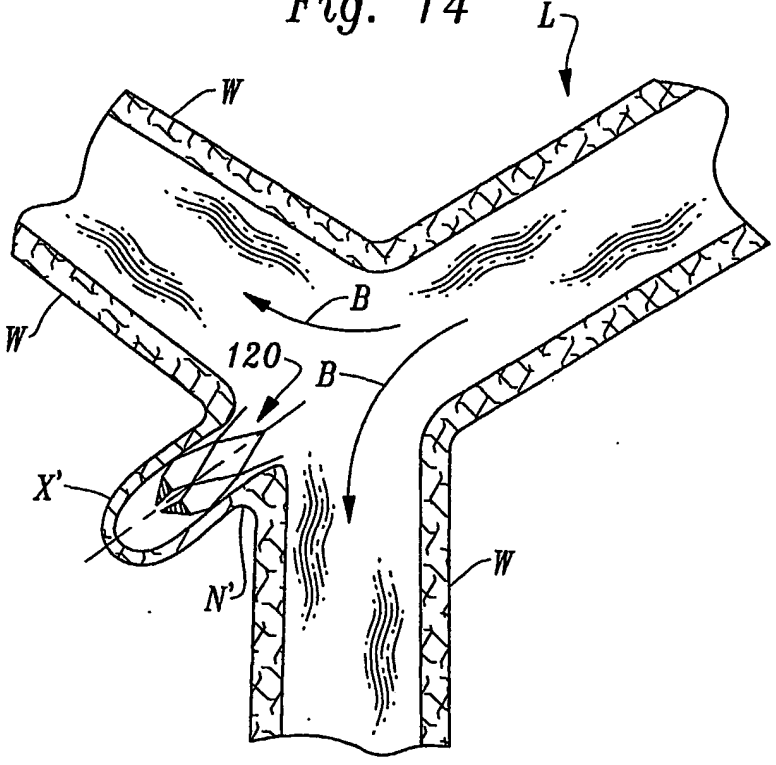

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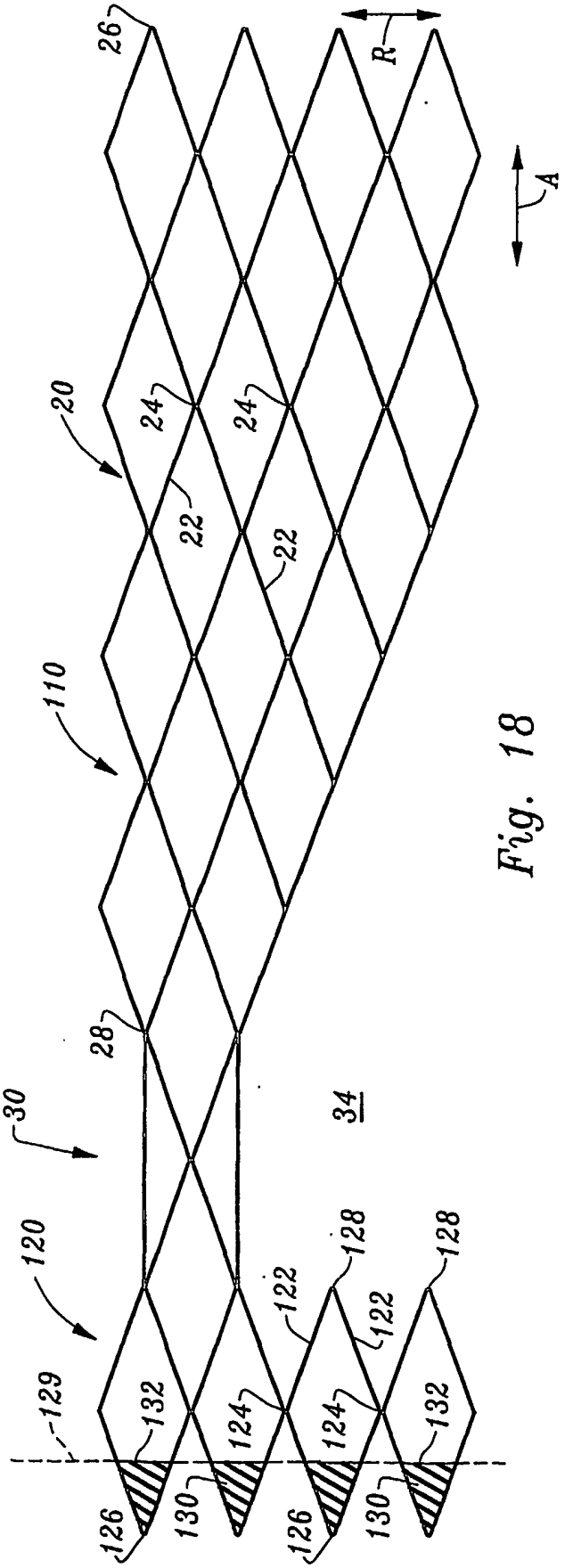
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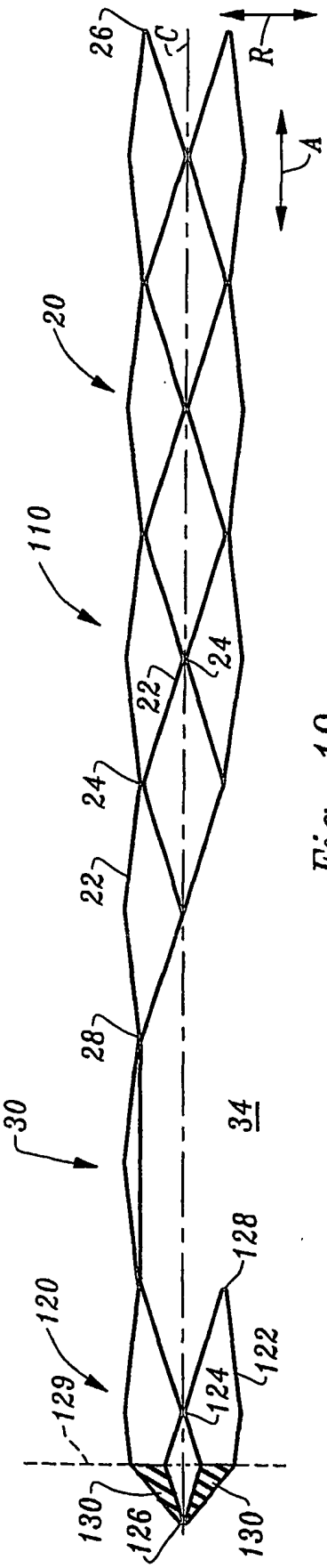
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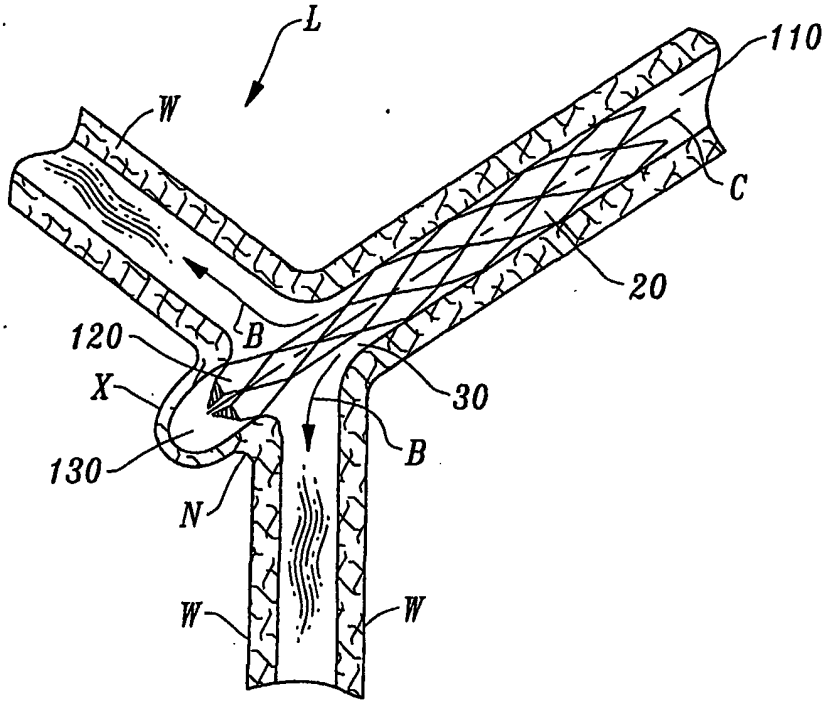
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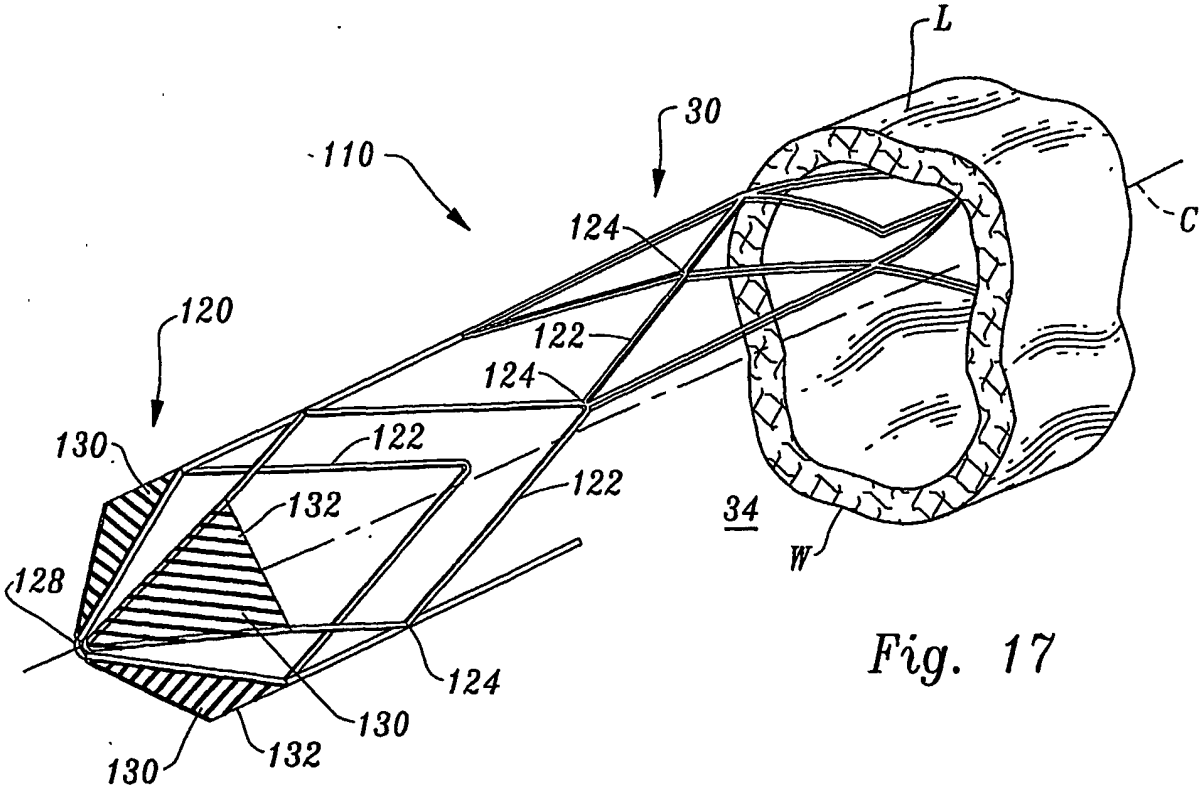
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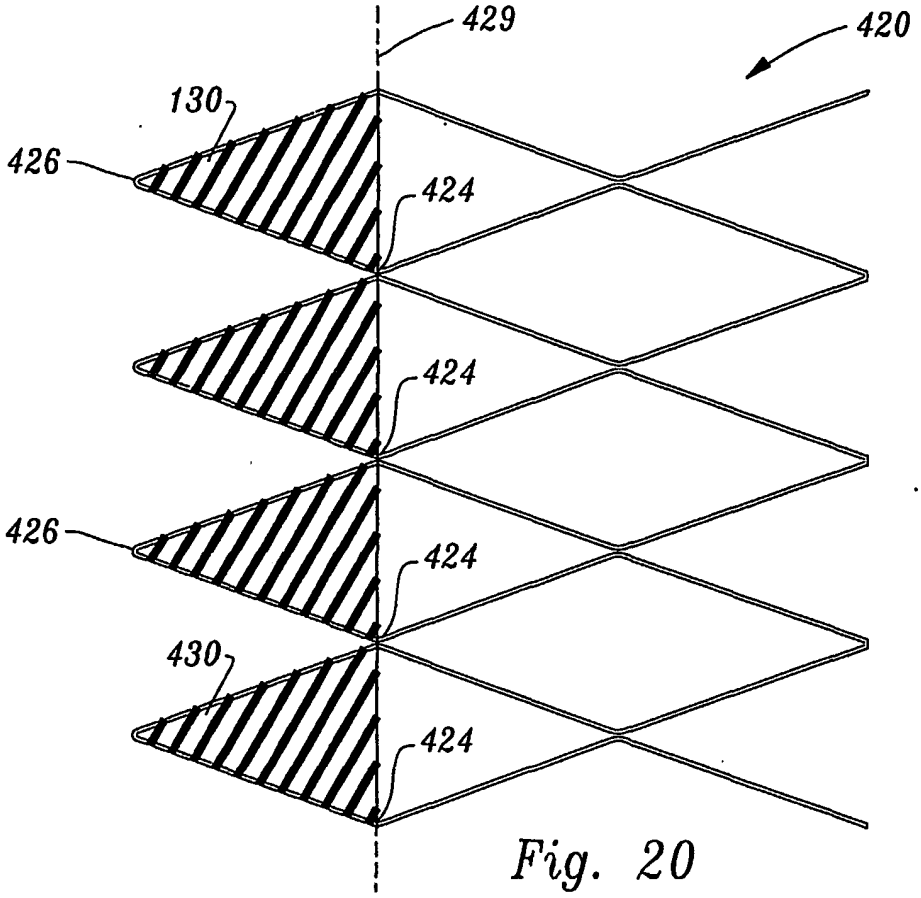
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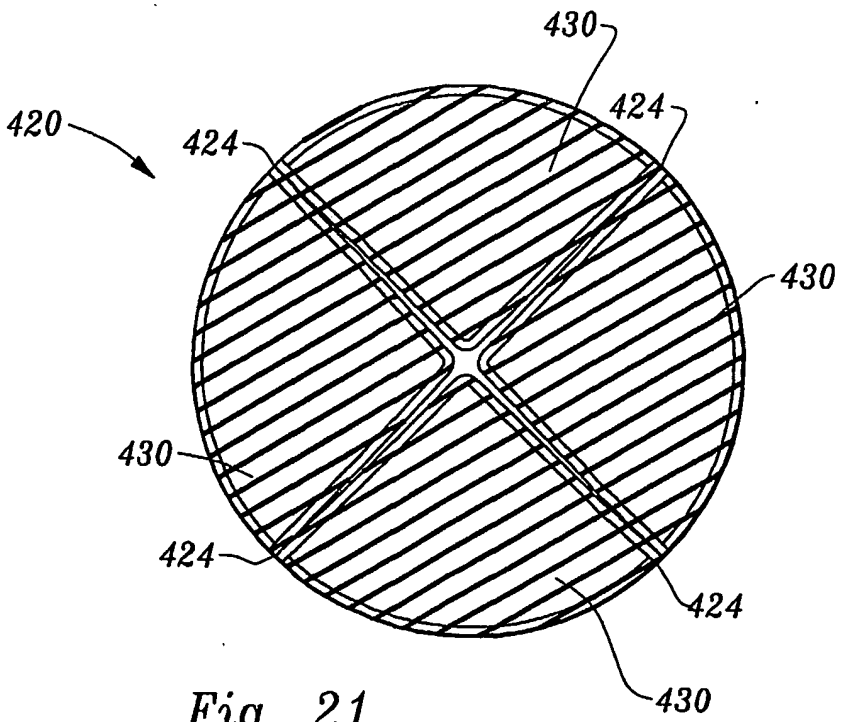
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Fig. 21

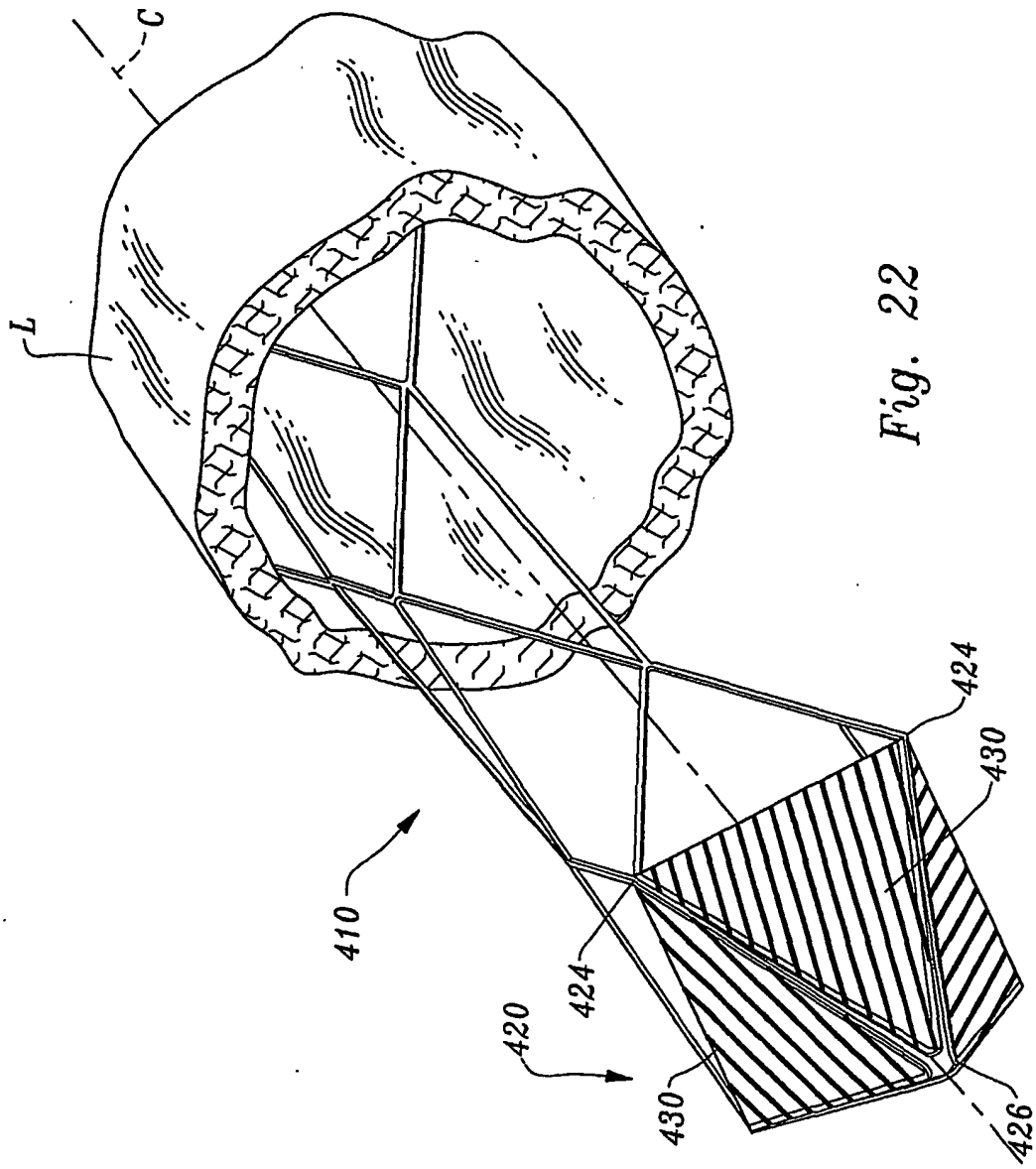

Fig. 22

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61F 2/06; A61M 29/00

US CL : 623/1.11-1.15; 606/191-200

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/1.11-1.15; 606/191-200

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

None

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X — Y	US 6,152,144 A (LESH et al.) 28 November 2000, see figs. 1-7.	1-4, 11-16 --- 5, 17

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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Date of the actual completion of the international search 15 AUGUST 2001	Date of mailing of the international search report 05 NOV 2001
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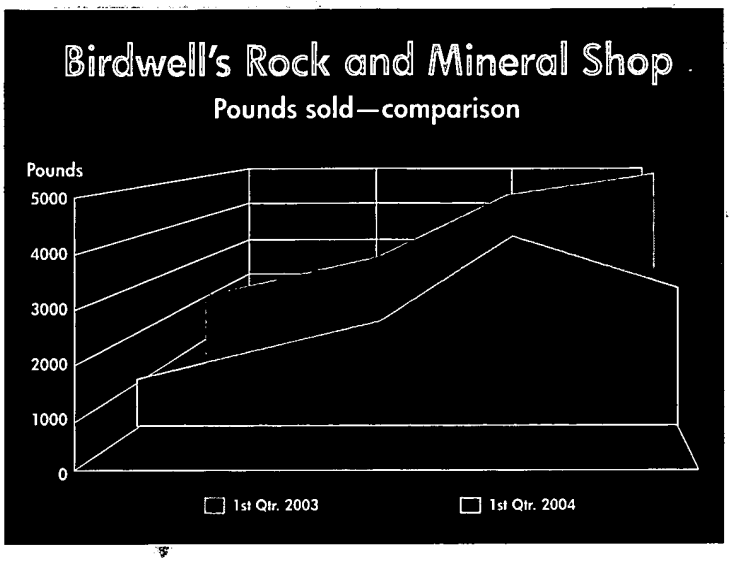

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(74) Agent: **HEISLER, Bradley, P.**; Heisler & Associates, Suite 300, 3017 Douglas Boulevard, Roseville, CA 95661 (US).

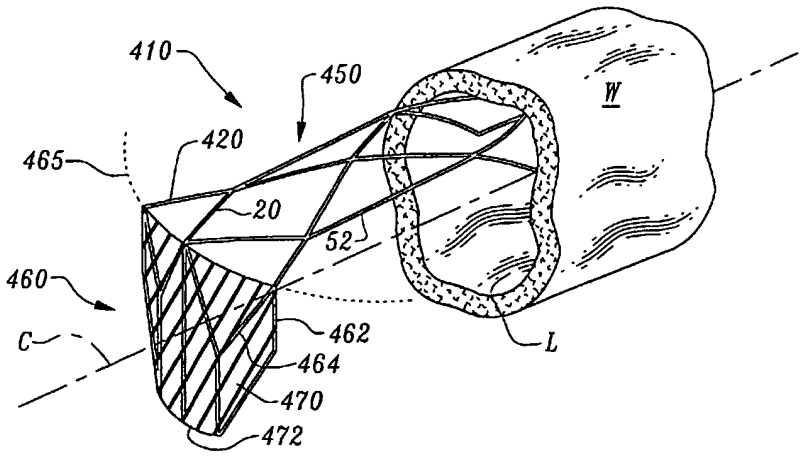
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: RADIALLY EXPANDABLE STENT FEATURING COVERING TIP PRIMARILY FOR BIFURCATED ARTERY ANEURYSMS



(57) Abstract: A radially expandable stent (10) is provided with a generally cylindrical contour between a distal end (12) and a proximal end (14). The distal end (12) includes a covering tip (60) attached to other portions of the stent (10) through an extension (50) spanning a gap (50) near the distal end (12) of the stent (10). The covering tip (60) extends partially away from the cylindrical contour of the stent (10) and toward a center line of the stent (10). The covering tip (60) includes a surface layer (70) which precludes blood and other fluid flow through the covering tip (60). The stent (10) is formed with a material having a bias towards a final expanded configuration with the covering tip (60) extending away from the cylindrical contour towards the centerline C of the stent (10). The stent (10) is sufficiently flexible so that the covering tip (60) can be initially oriented axially when in an original collapsed configuration and then angled towards the centerline C when the stent (10) is radially expanded. The covering tip (60) can be oriented blocking a neck N of an aneurysm X which faces a blood vessel or other body lumen L. The stent (10) radially expands to engage walls W of the body lumen L with the covering tip (60) blocking the neck N of the aneurysm X so that expansion or rupture of the aneurysm X is precluded.

WO 01/93782 A1